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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,515	06/16/2006	Francesca Frigerio	PC/4-32727A	9099

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EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,515	FRIGERIO ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 17-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16* is/are rejected.

7)☒ Claim(s) *12 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0606*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election, without traverse, of Invention V, and sub-invention (G) modulator of enzyme activity, in their response of April 14, 2008 is acknowledged. The elected invention is directed to a method of treating obesity using an S6 kinase activity inhibitor and is encompassed by Claims 12-16. Claims 1-26 are pending. Claims 1-11 and 17-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 12-16 are hereby examined.

Priority

The priority date granted for the instant invention is as follows. Claims 12 and 13 are granted the priority date of October 18, 2002, the filing date of UK 0224338.4, which disclosed the subject matter of said claims. Claims 14-16 are granted the priority date of August 22, 2003, the filing date of US 60/497,277, which disclosed the subject matter of said claims.

Information Disclosure Statement

The Information Disclosure Statement filed June 16, 2006 cites documents that have not been filed with the office; documents AM, AN , AO, and AQ. The Information Disclosure Statement has been placed in the application file, but said references have not been considered. If Applicants wish for the references therein to be considered, a supplemental Information Disclosure Statement and the documents should be submitted. Any subsequent rejection, based on consideration of the supplemental Information Disclosure Statement, will not be considered new grounds for rejection.

Claims-Objections

Claims 12 and 13 are objected to for reciting non-elected subject matter.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Double Patenting

> The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
>
> A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).
>
> An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 12-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 13-17 of US Application US 10/568,637. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 12-16 herein and Claims 13-17 of 10/568,637 are both directed to methods for treating weight-related conditions. The claims differ in that Claims 13-17 of 10/568,637 specifically recite methods for treating weight-related insulin resistance/diabetes, while Claims 12-16 herein recite methods for treating weight-related conditions dependent on fat accumulation. The portion of the specification in 10/568,637 that supports the recited methods includes embodiments that would anticipate Claims 12-16 herein, e.g., methods for treating weight-related conditions dependent on fat accumulation, which are also methods encompassed

by Claims 13-17 of 10/568,637. Claims 12-16 herein cannot be considered patentably distinct over Claims 13-17 of 10/568,637 when there are specifically recited embodiments (methods for treating weight-related insulin resistance/diabetes) that would anticipate Claims 12-16 herein. Alternatively, Claims 12-16 herein cannot be considered patentably distinct over Claims 13-17 of 10/568,637 when there are specifically disclosed embodiments in 10/568,637 that supports Claims 13-17 of that application and falls within the scope of Claims 12-16 herein, because it would have been obvious to a skilled artisan to modify the methods of Claims 13-17 of 10/568,637 by selecting a specifically disclosed embodiment that supports those claims, i.e., methods for treating weight-related insulin resistance/diabetes, as disclosed in 10/568,637. One having ordinary skill in the art would have been motivated to do this, because such an embodiment, is disclosed as being a preferred embodiment within Claims 13-17 of the other application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 12-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preventing a weight disorder in mice by deleting the S6 kinase-encoding gene, does not reasonably provide enablement for any method of treating or preventing

any weight disorder by using any agent that affects any S6 kinase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 12 and 13 are so broad as to encompass any method for treating any weight-associated disorder in any subject using any agent that is a S6 kinase activity modulator. Claim 14 is so broad as to encompass any method for treating any weight-associated disorder in any subject using any agent that is a S6 kinase activity modulator, wherein said agent binds to an ATP binding site. Claim 15 is so broad as to encompass any method for treating any weight-associated disorder in any subject using any agent that is a S6 kinase activity modulator, wherein said agent binds to a catalytic domain. Claim 16 is so broad as to encompass any method for treating any weight-associated disorder in any subject using any agent that is a S6 kinase activity modulator, wherein said agent is an antibody. The scope of each of these claims is not

commensurate with the enablement provided by the disclosure with regard to the extremely large number of methods broadly encompassed by the claim. The specific reagents and steps used for treating a weight disorder determine the method's success. Predictability of which steps and reagents can be used to obtain the effect requires a knowledge of, and guidance with regard to how said steps and reagents relate to the desired modulation of S6 kinase activity such as to treat or prevent any weight disorder as well as which subjects to treat. However, in this case the disclosure is limited to a method for preventing a weight disorder in mice by deleting the S6 kinase-encoding gene.

While biochemical, cellular, and in vivo methods for screening for compounds that modulate S6 kinase are known, it is not routine in the art to screen an essentially unlimited number of agents for modulating S6 kinase in such assay. Moreover, it is not routine in the art to screen any discovered inhibitors of S6 kinase for treatment or prevention of any weight-related disorder in any subject. Those agents to be used for successful treatment as well as which disorders and subjects to treat remain unpredictable. The specification fails to teach the skilled artisan even one successful method of treating a weight-related disorder by administering an agent to a subject, wherein the agent is a modulator of S6 kinase activity. Even if the specification did teach a successful method, which it does not, one skilled in the art would expect any tolerance to modification of the steps and reagents used in a successful method would diminish with increasing and additional modifications of steps and reagents used.

The specification does not support the broad scope of Claims 12 and 13, which encompasses all methods for treating any weight-associated disorder in any subject using any agent that is a S6 kinase activity modulator. The specification does not support the broad scope

of Claim 14, which encompasses all methods for treating any weight-associated disorder in any subject using any agent that is a S6 kinase activity modulator, wherein said agent binds to an ATP binding site. The specification does not support the broad scope of Claim 15, which encompasses all methods for treating any weight-associated disorder in any subject using any agent that is a S6 kinase activity modulator, wherein said agent binds to a catalytic domain. The specification does not support the broad scope of Claim 16, which encompasses all methods for treating any weight-associated disorder in any subject using any agent that is a S6 kinase activity modulator, wherein said agent is an antibody. The specification does not support the broad scope of Claims 12-16 because the specification does not establish: (A) any successful method of treating a weight-related disorder by administering an agent to a subject, wherein the agent is a modulator of any S6 kinase activity; (B) the structure, doses, and routes of administration for any agents that can be successfully used in the recited method; (C) a rational and predictable scheme for modifying the structure of any agent, or doses thereof, with an expectation of obtaining the desired biological functions; (D) subjects and specific disorders to be treated by the recited method; (E) a rational and predictable scheme for predicting which subjects and specific disorders can be successfully treated with which agents in which subjects; and (F) the specification provides insufficient guidance as to which of the essentially infinite possible choices of agents, doses, routes of administration is likely to be successful used treating an essentially infinite possible choices of subjects and disorders using the recited method.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of methods of treating or preventing any weight

disorder by using any steps and agents that affects any S6 kinase activity. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Claims 12-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 12-16 are directed to a genus of methods for treating or preventing any weight disorder by using any steps and agents that affects any S6 kinase activity in any subject. The specification teaches no such methods. Given this lack of description of representative species encompassed by the genera of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bjorbaek et al, 2000 (IDS) in view of Diggle et al, 1996 and Damoiseaux et al, 1996. Bjorbaek et al teaches that deletion of the gene encoding S6 kinase results in reduced body weight and body fact (Fig 5 & 8). Bjorbaek et al do not teach administration of a S6 kinase activity inhibitor to reduce body weight and body fact. Diggle et al teach that rapamycin is a S6 kinase activity inhibitor that affects insulin-stimulated signal transduction (Figs 2; Table 1), while Damoiseaux et al teaches in vivo administration of rapamycin (pg 996, parg 6;). It would have been obvious to a person of ordinary skill in the art to administer the S6 kinase activity inhibitor rapamycin as means for treating or preventing a weight disorder dependent on fat accumulation. Motivation to do so derives from the desire to treat or prevent obesity. The expectation of success is high, as inhibition of S6 kinase is known to reduce body weight and body fact and rapamycin is a known inhibitor of S6 kinase that can be administered in vivo. Therefore, Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bjorbaek et al, 2000 (IDS) in view of Diggle et al, 1996 and Damoiseaux et al, 1996.

Allowable Subject Matter

No claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-092834. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sheridan Swope/
Primary Examiner, 1652